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§ 484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 2329, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995]

§ 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

- (a) Standards: Retention of records. Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.
- (b) Standards: Protection of records. Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

 $[54 \ FR \ 33367, \ Aug. \ 14, \ 1989, \ as \ amended \ at \ 60 \ FR \ 65498, \ Dec. \ 20, \ 1994]$

§ 484.52 Condition of participation: Evaluation of the agency's program.

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

- (a) Standard: Policy and administrative review. As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.
- (b) Standard: Clinical record review. At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

 $[54~\mathrm{FR}~33367,~\mathrm{Aug}.~14,~1989;~66~\mathrm{FR}~32778,~\mathrm{June}~18,~2001]$

§ 484.55 Condition of participation: Comprehensive assessment of pa-

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement

of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

- (a) Standard: Initial assessment visit. (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.
- (2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.
- (b) Standard: Completion of the comprehensive assessment. (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.
- (2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.
- (3) When physical therapy, speechlanguage pathology, or occupational therapy is the only service ordered by the physician, a physical therapist,

- speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.
- (c) Standard: Drug regimen review. The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.
- (d) Standard: Update of the comprehensive assessment. The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—
- (1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—
 - (i) Beneficiary elected transfer;
- (ii) Significant change in condition resulting in a new case-mix assignment; or
- (iii) Discharge and return to the same HHA during the 60-day episode.
- (2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;
 - (3) At discharge.
- (e) Standard: Incorporation of OASIS data items. The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data

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items collected at inpatient facility admission or discharge only.

[64 FR 3784, Jan. 25, 1999, as amended at 65 FR 41211, July 3, 2000]

Subpart D [Reserved]

Subpart E—Prospective Payment System for Home Health Agencies

SOURCE: 65 FR 41212, July 3, 2000, unless otherwise noted.

§484.200 Basis and scope.

- (a) *Basis*. This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.
- (b) *Scope*. This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§ 484.202 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speechlanguage pathology services, and medical social services).

Home health market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

Rural area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in §412.64(b)(1)(ii)(C) of this chapter.

Urban area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter

[70 FR 68142, Nov. 9, 2005]

§ 484.205 Basis of payment.

- (a) Method of payment. An HHA receives a national prospective 60-day episode payment of a predetermined rate for a home health service previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national 60-day episode payment is determined in accordance with §484.215. The national prospective 60-day episode payment is subject to the following adjustments and additional payments:
- (1) A low-utilization payment adjustment (LUPA) of a predetermined pervisit rate as specified in §484.230.
- (2) A partial episode payment (PEP) adjustment due to an intervening event defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with §484.235.
- (3) A significant change in condition (SCIC) payment adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. The SCIC adjustment is determined in accordance with §484.237.
- (4) An outlier payment is determined in accordance with §484.240.
- (b) Episode payment. The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in §484.230, a partial episode payment adjustment set forth at §484.235, a significant change in condition payment set forth at §484.237, or an additional outlier payment set forth in §484.240. All payments under this